Complete Summary

GUIDELINE TITLE

Clinical practice guideline: management of sinusitis.

BIBLIOGRAPHIC SOURCE(S)

Clinical practice guideline: management of sinusitis. Pediatrics 2001 Sep;108(3):798-808. [79 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Uncomplicated, acute, subacute, or recurrent bacterial sinusitis

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Allergy and Immunology
Family Practice
Internal Medicine
Otolaryngology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To evaluate and analyze the existing evidence for the diagnosis and treatment of acute uncomplicated sinusitis in children
- To formulate recommendations for health care providers regarding the diagnosis, evaluation, and treatment of children, ages 1 to 21 years, with uncomplicated acute, subacute, and recurrent acute bacterial sinusitis

TARGET POPULATION

Children, aged 1 to 21 years, with uncomplicated acute, subacute, and recurrent acute bacterial sinusitis.

Note: Neonates and children younger than 1 year of age are not considered. Although bacterial sinusitis does occur rarely in children less than 1 year of age, their exclusion reflects, in part, the difficulty in conducting clinical investigation in this age group. This is a consequence of the small size of paranasal sinuses and the difficulty in safely performing sinus aspiration. This practice parameter does not apply to children with previously recognized anatomic abnormalities of their paranasal sinuses (facial dysmorphisms or trauma), immunodeficiencies, cystic fibrosis, or immotile cilia syndrome.

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/initial assessment

1. Physical examination and evaluation of symptoms
2. Evaluation of child for day care attendance
3. Transillumination of the sinuses
4. Sinus aspiration to recover bacteria in high density (considered but not recommended)
5. Imaging studies such as plain radiographs, computer tomography, or magnetic resonance imaging

Therapy of acute sinusitis

1. Amoxicillin
2. Cefdinir, cefuroxime, cefpodoxime, clarithromycin or azithromycin in cases of serious penicillin allergy (Note: azithromycin is not approved by the U.S. Food and Drug Administration for sinusitis treatment)
3. Clindamycin (for penicillin allergy and penicillin resistance)
4. Amoxicillin-clavulanate
5. Intravenous cefotaxime or ceftriaxone

6. Trimethoprim-sulfamethoxazole and erythromycin-sulfisoxazole (considered but not recommended)
    - Note: The following treatments are considered but not recommended: adjuvant therapies, such as saline nasal irrigation, antihistamines, and decongestants, intranasal steroids (budesonide, flunisolide); mucolytics; antibiotic prophylaxis; and alternative or complementary medicines such as vitamins C, Echinacea preparations, and zinc nasal gel

Management of complications, including referral to otolaryngologist, ophthalmologist, or neurosurgeon

MAJOR OUTCOMES CONSIDERED

- Clinical improvement rates for intervention studies of antibiotics or ancillary measures
- Concordance of diagnostic tests (expressed as likelihood ratios)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Medline was searched using a broad search strategy covering from January 1966 through March 1999. The word sinusitis was used in the search as a text word and as a medical subject heading. The search results were then limited to human studies and English language studies that included pediatric patients using the terms "infant, newborn," "infant," "child, preschool," "child," and "adolescence." The titles and abstracts of the citations produced by the search were screened for articles that may have data on treatment of acute sinusitis in the pediatric population.

As part of a previous project, the authors of the guideline also had retrieved all published randomized, controlled trials on the management of acute uncomplicated sinusitis in all age groups. This collection of randomized, controlled trials had been generated based on Medline searches complemented by Excerpta Medica searches, perusal of the Abstracts for the Interscience Conference on Antimicrobial Agents and Chemotherapy, review of bibliographies of retrieved studies, and communication with technical experts and colleagues in the field. Randomized, controlled trials were included in this collection with no foreign language restrictions. All identified randomized, controlled trials were screened for the presence of data in children.

NUMBER OF SOURCE DOCUMENTS

21

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Given the paucity and heterogeneity of the data for specific questions, the guideline developers did not attempt the application of formal meta-analytic techniques. When possible, rates were combined across different studies and heterogeneity was assessed with a chi-squared statistic. Odds ratios for efficacy (clinical improvement) also were estimated by the Mantel-Haenzel formula stratified per antibiotic use.

For diagnostic modalities, concordance was expressed by using the possible likelihood ration, which is calculated as:

positive likelihood ratio = sensitivity/(1 - specificity)

and the negative likelihood ratio, which is calculated as:

negative likelihood ratio = (1 - sensitivity)/specificity

The positive likelihood ratio gives an estimate of how much more common a specific diagnostic finding in the positive group is versus the negative group, when positive and negative are defined by a different diagnostic standard. For example, a sensitivity of 50% with specificity of 90% corresponds to a positive likelihood ratio of 5. The higher the positive likelihood ratio, the better the concordance of the 2 diagnostic modalities. A positive likelihood ratio of 1 indicates that there is no concordance at all. There are no absolute cutoffs, but positive likelihood ratios between 1 and 5 are generally suggestive of poor concordance, while positive likelihood ratios >20 suggest strong concordance. The positive likelihood ratio can take values up to infinity. The inverse considerations hold true for the negative likelihood ratio, where good concordance is shown by diminishing values. A negative likelihood ratio of 1 also shows lack of concordance. Again, there are no absolute cutoffs, but negative likelihood ratios between 0.2 and 1 are generally suggestive of poor concordance, while negative likelihood ratios <0.05 suggest strong concordance.

All reported P values are 2-tailed.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strong recommendations were based on high-quality scientific evidence or, when such was unavailable, strong expert consensus

Fair and weak recommendations are based on lesser-quality or limited data and expert consensus

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Several groups in addition to the subcommittee (composed of pediatricians with expertise in infectious disease, allergy, epidemiology, family practice, and pediatric practice, supplemented with an otolaryngologist and radiologist) reviewed and revised this guideline. Included in the groups were members of the American College of Emergency Physicians, American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Asthma, Allergy and Immunology, as well as numerous national committees and sections of the American Academy of Pediatrics.

Three specific issues were considered: (1) evidence for the efficacy of various antibiotics in children; (2) evidence for the efficacy of various ancillary, nonantibiotic regimens; and (3) the diagnostic accuracy and concordance of clinical symptoms, radiography (and other imaging methods), and sinus aspiration.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Methods of Diagnosis

Under normal circumstances the paranasal sinuses are assumed to be sterile. However, the paranasal sinuses are in continuity with surface areas, such as the

nasal mucosa and nasopharynx, which are heavily colonized with bacteria. Although it is reasonable to assume that the paranasal sinuses are frequently and transiently contaminated by bacteria from neighboring surfaces, these bacteria, which are present in low density, are probably removed by the normal function of the mucociliary apparatus. Accordingly, the gold standard for the diagnosis of acute bacterial sinusitis is the recovery of bacteria in high density ($\geq 10^4$ colony-forming units/mL) from the cavity of a paranasal sinus. Although sinus aspiration is the gold standard for the diagnosis of acute bacterial sinusitis, it is an invasive, time-consuming, and potentially painful procedure that should only be performed by a specialist (otolaryngologist). It is not a feasible method of diagnosis for the primary care practitioner and is not recommended for the routine diagnosis of bacterial sinus infections in children. However, the results of sinus aspiration have been correlated with clinical and radiographic findings in children with acute respiratory symptoms.

Recommendation 1

The diagnosis of acute bacterial sinusitis is based on clinical criteria in children who present with upper respiratory symptoms that are either persistent or severe (strong recommendation based on limited scientific evidence and strong consensus of the panel).

Acute bacterial sinusitis is an infection of the paranasal sinuses lasting less than 30 days that presents with either persistent or severe symptoms. Patients are asymptomatic after recovery from episodes of acute bacterial sinusitis.

Persistent symptoms are those that last longer than 10 to 14, but less than 30, days. Such symptoms include nasal or postnasal discharge (of any quality), daytime cough (which may be worse at night), or both.

Severe symptoms include a temperature of at least 102Â°F (39Â°C) and purulent nasal discharge present concurrently for at least 3 to 4 consecutive days in a child who seems ill. The child who seems toxic should be hospitalized and is not considered in this algorithm.

Uncomplicated viral upper respiratory infections generally last 5 to 7 days but may last longer. Although the respiratory symptoms may not have completely resolved by the 10th day, almost always they have peaked in severity and begun to improve. Therefore, the persistence of respiratory symptoms without any evidence that they are beginning to resolve suggests the presence of a secondary bacterial infection. Significant fever or complaints of facial pain or headache are variable. It is important for the practitioner to attempt to differentiate between sequential episodes of uncomplicated viral upper respiratory tract infections (which may seem to coalesce in the mind of the patient or parent) from the onset of acute sinusitis with persistent symptoms. The objective of treatment of acute bacterial sinusitis is to foster rapid recovery, prevent suppurative complications, and minimize exacerbations of asthma (reactive airways diseases).

Children with acute bacterial sinusitis who present with severe symptoms need to be distinguished from those with uncomplicated viral infections who are moderately ill. If fever is present at all in uncomplicated viral infections of the upper respiratory tract, it tends to be present early in the illness, usually

accompanied by other constitutional symptoms such as headache and myalgias. Generally, the constitutional symptoms resolve in the first 48 hours and then the respiratory symptoms become prominent. In most uncomplicated viral infections, purulent nasal discharge does not appear for several days. Accordingly, it is the concurrent presentation with high fever and purulent nasal discharge for at least 3 to 4 consecutive days that helps to define the severe presentation of acute bacterial sinusitis. Children with severe onset of acute bacterial sinusitis may have an intense headache that is above or behind the eye; in general, they seem to be moderately ill.

Unfortunately, the physical examination does not generally contribute substantially to the diagnosis of acute bacterial sinusitis. This is explained by the similarity of physical findings in the patient with an uncomplicated viral rhinosinusitis and the patient with acute bacterial sinusitis. In both instances, examination of the nasal mucosa may show mild erythema and swelling of the nasal turbinates with mucopurulent discharge. Facial pain is an unusual complaint in children. Facial tenderness is a rare finding in small children and may be unreliable as an indicator of acute bacterial sinusitis in older children and adolescents. Reproducible unilateral pain, present on percussion or direct pressure over the body of the frontal and maxillary sinuses, may indicate a diagnosis of acute bacterial sinusitis. Likewise, observed or reported periorbital swelling is suggestive of ethmoid sinusitis. Examination of the tympanic membranes, pharynx, and cervical lymph nodes does not usually contribute to the diagnosis of acute bacterial sinusitis.

The value of the performance of transillumination of the sinuses to assess whether fluid is present in the maxillary and frontal paranasal sinuses is controversial. The technique is performed in a completely darkened room (after the examiner's eyes are adapted to the dark) by placing a transilluminator (high-intensity light beam) either in the mouth or against the cheek (for the maxillary sinuses) or under the medial aspect of the supraorbital ridge area (for the frontal sinuses) to assess the transmission of light through the sinus cavity. Transillumination is difficult to perform correctly and has been shown to be unreliable in children younger than 10 years. In the older child it may be helpful at the extremes of interpretation; if transillumination is normal, sinusitis is unlikely; if the transmission of light is absent, the maxillary or frontal sinus is likely to be filled with fluid.

Subacute sinusitis is defined by the persistence of mild to moderate and often intermittent respiratory symptoms (nasal discharge, daytime cough, or both) for between 30 and 90 days. The nasal discharge may be of any quality, and cough is often worse at night. Low-grade fever may be periodic but is usually not prominent. The microbiology of subacute sinusitis is the same as that observed in patients with acute bacterial sinusitis.

Patients with recurrent acute bacterial sinusitis are defined as having had 3 episodes of acute bacterial sinusitis in 6 months or 4 episodes in 12 months. The response to antibiotics is usually brisk and the patient is completely free of symptoms between episodes.

The most common cause of recurrent sinusitis is recurrent viral upper respiratory infection, often a consequence of attendance at day care or the presence of an older school-age sibling in the household. Other predisposing conditions include

allergic and nonallergic rhinitis, cystic fibrosis, an immunodeficiency disorder (insufficient or dysfunctional immunoglobulins), ciliary dyskinesia, or an anatomic problem.

Recommendation 2a

Imaging studies are not necessary to confirm a diagnosis of clinical sinusitis in children $\leq$6 years of age (strong recommendation based on limited scientific evidence and strong consensus of the panel).

In 1981, children between the ages of 2 and 16 years presenting with either persistent or severe symptoms were evaluated with sinus radiographs. When children with persistent or severe symptoms were found to have abnormal sinus radiographs (complete opacification, mucosal thickening of at least 4 mm, or an air-fluid level), an aspiration of the maxillary sinus was performed. Bacteria in high density ($\geq 10^4$ colony-forming units/mL) were recovered in 70% to 75% of the children. This proportion of positive cultures (75%) is similar to the likelihood that a tympanocentesis will yield middle ear fluid with a positive culture for bacteria in children with otoscopic evidence of acute otitis media.

In children with persistent symptoms, the history of protracted respiratory symptoms (>10 but <30 days without evidence of improvement) predicted significantly abnormal radiographs (complete opacification, mucosal thickening of at least 4 mm, or an air-fluid level) in 80% of children. For children 6 years of age or younger, the history predicted abnormal sinus radiographs in 88% of children. For children older than 6 years, the history of persistent symptoms predicted abnormal sinus radiographs in 70%. The peak age for acute bacterial sinusitis is in children 6 years of age or younger. Accordingly, in this age group, because a positive history predicts the finding of abnormal sinus radiographs so frequently (and because history plus abnormal radiographs results in a positive sinus aspirate in 75% of cases), radiographs can be safely omitted and a diagnosis of acute bacterial sinusitis can be made on clinical criteria alone. Approximately 60% of children with symptoms of sinusitis (persistent or severe) will have bacteria recovered from an aspirate of the maxillary sinus.

In contrast to the general agreement that radiographs are not necessary in children 6 years of age or younger with persistent symptoms, the need for radiographs as a confirmatory test of acute sinusitis in children older than 6 years with persistent symptoms and for all children (regardless of age) with severe symptoms is controversial. Some practitioners may elect to perform sinus radiographs with the expectation or suspicion that the study may be normal. A normal radiograph is powerful evidence that bacterial sinusitis is not the cause of the clinical syndrome. However, the American College of Radiology has taken the position that the diagnosis of acute uncomplicated sinusitis should be made on clinical grounds alone. They support this position by noting that plain radiographs of the paranasal sinuses are technically difficult to perform, particularly in very young children. Correct positioning may be difficult to achieve and therefore the radiographic images may overestimate and underestimate the presence of abnormalities within the paranasal sinuses. The college would reserve the use of images for situations in which the patient does not recover or worsens during the course of appropriate antimicrobial therapy. Similarly, a recent set of guidelines generated by the Sinus and Allergy Health Partnership (representing numerous

constituencies) does not recommend either radiographs or computed tomography (CT) or magnetic resonance imaging scans to diagnose uncomplicated cases of acute bacterial sinusitis in any age group.

It is essential to recognize that abnormal images of the sinuses (either radiographs, computed tomography, or magnetic resonance imaging) cannot stand alone as diagnostic evidence of acute bacterial sinusitis under any circumstances. Images can serve only as confirmatory measures of sinus disease in patients whose clinical histories are supportive of the diagnosis. Numerous investigations have demonstrated the high frequency of abnormal images in the paranasal sinuses of children undergoing imaging for indications other than suspected sinusitis. In a study by Glasier et al. (Glasier CM, Mallory GB, Steele RW. Significance of opacification of the maxillary and ethmoid sinuses in infants. J Pediatr 1989;114:45-50), almost 100% of young children who were undergoing computed tomography examination for reasons other than sinus disease and who had an upper respiratory tract infection in the previous 2 weeks demonstrated soft tissue changes in their sinuses. A study by Gwaltney et al in 1994 (Gwaltney JM Jr, Phillips CD, Miller RD, Riker DK. Computed tomographic study of the common cold. N Engl J Med 1994;330:25-30) found that abnormalities of the paranasal sinuses on computed tomography scan are extremely common in young adults with acute (<72 hours) uncomplicated viral upper respiratory infections. This study and others serve to underscore that when abnormalities of the mucosa are present on images they indicate the presence of inflammation but do not disclose whether the inflammatory process is caused by viral infection, bacterial infection, allergy, or chemical irritation (e.g., chlorine exposure in the swimmer).

Recommendation 2b

Computed tomography scans of the paranasal sinuses should be reserved for patients in whom surgery is being considered as a management strategy (strong recommendation based on good evidence and strong panel consensus).

Despite the limitations of computed tomography scans, they offer a detailed image of sinus anatomy and, when taken in conjunction with clinical findings, remain a useful adjunct to guide surgical treatment. Computed tomography scans are indicated in children who present with complications of acute bacterial sinus infection or those who have very persistent or recurrent infections that are not responsive to medical management. In these instances, the image, preferably a complete computed tomography scan of the paranasal sinuses, is essential to provide precise anatomic information to the clinician. These are instances in which the physician may be contemplating surgical intervention, including aspiration of the paranasal sinuses.

Recommendation 3

Antibiotics are recommended for the management of acute bacterial sinusitis to achieve a more rapid clinical cure (strong recommendation based on good evidence and strong panel consensus).

To promote the judicious use of antibiotics, it is essential that children diagnosed as having acute bacterial sinusitis meet the defining clinical presentations of

"persistent" or "severe" disease as described previously. This will minimize the number of children with uncomplicated viral upper respiratory tract infections who are treated with antimicrobials.

In a study comparing antimicrobial therapy with placebo in the treatment of children with the clinical and radiographic diagnosis of acute bacterial sinusitis, children receiving antimicrobial therapy recovered more quickly and more often than those receiving placebo. On the third day of treatment, 83% of children receiving an antimicrobial were cured or improved compared with 51% of the children in the placebo group. (Forty-five percent of children receiving antimicrobial therapy were cured [complete resolution of respiratory symptoms] compared with 11% receiving placebo.) On the 10th day of treatment, 79% of children receiving an antimicrobial were cured or improved compared with 60% of children receiving placebo. Approximately 50% to 60% of children will improve gradually without the use of antimicrobials; however, the recovery of an additional 20% to 30% is delayed substantially compared with children who receive appropriate antibiotics.

A recent study by Garbutt et al. (Garbutt JM, Goldstein M, Gellman E, Shannon W, Littenberg B. A randomized, placebo-controlled trial of antimicrobial treatment for children with clinically diagnosed acute sinusitis. Pediatrics 2001;107:619-625) has challenged the notion that children identified as having acute sinusitis on clinical grounds alone (without the performance of images) will benefit from antimicrobial therapy. When children randomized to low-dose antibiotic therapy were compared with those receiving placebo there were no differences observed in outcome, either in the timing or frequency of recovery. The discrepancy in results between this investigation and the Wald study may be attributable to the inclusion in this study of a larger cohort of older children (who may not have had sinusitis) and the exclusion of more seriously ill children with a temperature >39Â°C or facial pain. Current recommendations for antibiotic management of uncomplicated sinusitis vary depending on a previous history of antibiotic exposure (in the previous 1-3 months), attendance at day care, and age. Some of the children in the Garbutt study might have qualified for high-dose amoxicillin-clavulanate to overcome antimicrobial resistant pathogens.

Comparative bacteriologic cure rates in studies of adults with acute sinusitis indicate the efficacy of antimicrobial treatment. The findings of these studies indicate that antimicrobials in adequate doses with appropriate antibacterial spectra are highly effective in eradicating or substantially reducing bacteria in the sinus cavity, whereas those with inadequate spectrum or given in inadequate doses are not (see Table 1 in the original guideline document).

The microbiology of acute, subacute, and recurrent acute bacterial sinusitis has been outlined in several studies. The principal bacterial pathogens are Streptococcus pneumoniae, nontypeable Haemophilus influenzae, and Moraxella catarrhalis. Streptococcus pneumoniae is recovered from approximately 30% of children with acute bacterial sinusitis, whereas Haemophilus influenzae and Moraxella catarrhalis are each recovered from about 20%. In the remaining 30% of children, aspirates of the maxillary sinus are sterile. It is noteworthy that neither Streptococcus aureus nor respiratory anaerobes are likely to be recovered from children with acute bacterial sinusitis.

Currently, approximately 50% of Haemophilus influenzae and 100% of Moraxella catarrhalis are likely to be beta-lactamase positive nationwide. Upper respiratory tract isolates of Streptococcus pneumoniae are not susceptible to penicillin in 15% to 38% (average 25%) of children; approximately 50% are highly resistant to penicillin and the remaining half are intermediate in resistance. The mechanism of penicillin resistance in Streptococcus pneumoniae is an alteration of penicillin binding proteins. This phenomenon, which varies considerably according to geographic location, results in resistance to penicillin and cephalosporin. Table 2 in the original guideline document shows the calculation for the likelihood that a child with acute bacterial sinusitis will harbor a resistant pathogen and not respond to treatment with amoxicillin. The following should be considered: the prevalence of each bacterial species as a cause of acute bacterial sinusitis, the prevalence of resistance among each bacterial species, and the rate of spontaneous improvement. Extrapolating from data derived from patients with acute otitis media, 15% of children with acute bacterial sinusitis caused by Streptococcus pneumoniae will recover spontaneously, half of the children with acute bacterial sinusitis caused by Haemophilus influenzae and half to three-quarters of the children infected with Moraxella catarrhalis also will recover spontaneously. Furthermore, only Streptococcus pneumoniae that are highly resistant to penicillin will not respond to conventional doses of amoxicillin. Accordingly, in the absence of any risk factors, approximately 80% of children with acute bacterial sinusitis will respond to treatment with amoxicillin. Risk factors for the presence of bacterial species that are likely to be resistant to amoxicillin include (1) attendance at day care, (2) recent receipt (<90 days) of antimicrobial treatment, and (3) age less than 2 years.

The desire to continue to use amoxicillin as first-line therapy in patients suspected of having acute bacterial sinusitis relates to its general effectiveness, safety, and tolerability; low cost; and narrow spectrum. For children younger than 2 years of age with uncomplicated acute bacterial sinusitis that is mild to moderate in degree of severity, who do not attend day care, and have not recently been treated with an antimicrobial, amoxicillin is recommended at either a usual dose of 45 mg/kg/d in 2 divided doses or a high dose of 90 mg/kg/d in 2 divided doses (see Figure 1 in the original guideline document). If the patient is allergic to amoxicillin, either cefdinir (14 mg/kg/d in 1 or 2 doses), cefuroxime (30 mg/kg/d in 2 divided doses), or cefpodoxime (10 mg/kg/d once daily) can be used (only if the allergic reaction was not a type 1 hypersensitivity reaction). In cases of serious allergic reactions, clarithromycin (15 mg/kg/d in 2 divided doses) or azithromycin (10 mg/kg/d on day 1, 5 mg/kg/d × 4 days as a single daily dose) can be used in an effort to select an antimicrobial of an entirely different class. The U.S. Food and Drug Administration has not approved azithromycin for use in patients with sinusitis. Alternative therapy in the penicillin-allergic patient who is known to be infected with a penicillin-resistant Streptococcus pneumoniae is clindamycin at 30 to 40 mg/kg/d in 3 divided doses.

Most patients with acute bacterial sinusitis who are treated with an appropriate antimicrobial agent respond promptly (within 48 to 72 hours) with a diminution of respiratory symptoms (reduction of nasal discharge and cough) and an improvement in general well-being. If a patient fails to improve, either the antimicrobial is ineffective or the diagnosis of sinusitis is not correct.

If patients do not improve while receiving the usual dose of amoxicillin (45 mg/kg/d), have recently been treated with an antimicrobial, have an illness that is moderate or more severe, or attend day care, therapy should be initiated with high-dose amoxicillin-clavulanate (80-90 mg/kg/d of amoxicillin component, with 6.4 mg/kg/d of clavulanate in 2 divided doses). This dose of amoxicillin will yield sinus fluid levels that exceed the minimum inhibitory concentration of all Streptococcus pneumoniae that are intermediate in resistance to penicillin and most, but not all, highly resistant Streptococcus pneumoniae. There is sufficient potassium clavulanate to inhibit all beta-lactamase producing Haemophilus influenzae and Moraxella catarrhalis. Alternative therapies include cefdinir, cefuroxime, or cefpodoxime. A single dose of ceftriaxone (at 50 mg/kg/d), given either intravenously or intramuscularly, can be used in children with vomiting that precludes administration of oral antibiotics. Twenty-four hours later, when the child is clinically improved, an oral antibiotic is substituted to complete the therapy. Although trimethoprim-sulfamethoxazole and erythromycin-sulfisoxazole have traditionally been useful in the past as first- and second-line therapy for patients with acute bacterial sinusitis, recent pneumococcal surveillance studies indicate that resistance to these 2 combination agents is substantial. Therefore, when patients fail to improve while receiving amoxicillin, neither trimethoprim-sulfamethoxazole nor erythromycin-sulfisoxazole are appropriate choices for antimicrobial therapy. For patients who do not improve with a second course of antibiotics or who are acutely ill, there are 2 options. It is appropriate to consult an otolaryngologist for consideration of maxillary sinus aspiration to obtain a sample of sinus secretions for culture and sensitivity so that therapy can be adjusted precisely. Alternatively, the physician may prescribe intravenous cefotaxime or ceftriaxone (either in hospital or at home) and refer to an otolaryngologist only if the patient does not improve on intravenous antibiotics. Some authorities recommend performing cultures of the middle meatus instead of aspiration of the maxillary sinus to determine the cause of acute bacterial sinusitis. However, there are no data in children that have correlated cultures of the middle meatus with cultures of the maxillary sinus aspirate.

The optimal duration of therapy for patients with acute bacterial sinusitis has not received systematic study. Often empiric recommendations are made for 10, 14, 21, or 28 days of therapy. An alternative suggestion has been made that antibiotic therapy be continued until the patient becomes free of symptoms and then for an additional 7 days. This strategy, which individualizes treatment for each patient, results in a minimum course of 10 days and avoids prolonged courses of antibiotics in patients who are asymptomatic and thereby unlikely to be compliant.

Adjuvant Therapies

No recommendations are made based on controversial and limited data.

Adjuvant therapies used to supplement the effect of antimicrobials have received relatively little systematic investigation. Available agents include saline nasal irrigation (hypertonic or normal saline), antihistamines, decongestants (topical or systemic), mucolytic agents, and topical intranasal steroids.

Currently there are no data to recommend the use of H1 antihistamines in nonallergic children with acute bacterial sinusitis. There is a single prospective

study in which children with presumed acute bacterial sinusitis were randomized to receive either decongestant-antihistamine or placebo in addition to amoxicillin. The active treatment group received topical oxymetazoline and oral decongestant-antihistamine syrup (brompheniramine and phenylpropanolamine*). No difference in clinical or radiographic resolution was noted between groups.

*Please Note: In June 2001, The Food and Drug Administration (FDA) issued a public health advisory for the use of phenylpropanolamine (PPA) and is taking steps to remove PPA from all drug products. They have also requested that all drug companies discontinue marketing products containing PPA. For more information on this public health advisory, please see the U.S. Food and Drug Administration Center for Drug Evaluation and Research (CDER) Web site.

There has been a single study of intranasal steroids as an adjunct to antibiotics in young children with presumed acute bacterial sinusitis. Intranasal budesonide spray had a modest effect on symptoms only during the second week of therapy. A multicenter, double-blind, randomized, parallel trial evaluating flunisolide spray as an adjunct to oral antibiotic therapy was reported in patients at least 14 years of age. The benefit of flunisolide was marginal and of minimal clinical importance. There is little reason to expect a substantial benefit from intranasal steroids in patients with acute bacterial sinusitis when antibiotics work effectively in the first 3 to 4 days of treatment.

No clinical trials of mucolytics have been reported in nonatopic children or adults with acute bacterial sinusitis. Neither saline nose drops nor nasal spray have been studied in patients with acute bacterial sinusitis. However, by preventing crust formation and liquefying secretions, they may be helpful. In addition, saline also may act as a mild vasoconstrictor of nasal blood flow. A method for performing a nasal saline flush was reported anecdotally by Schwartz (Schwartz RH. The nasal saline flush procedure. Pediatr Infect Dis J. 1997;291:664-667).

Antibiotic Prophylaxis

No recommendations are made based on limited and controversial data.

Antibiotic prophylaxis as a strategy to prevent infection in patients who experience recurrent episodes of acute bacterial sinusitis has not been systematically evaluated and is controversial. Although previously successful in children who experience recurrent episodes of acute otitis media, there is little enthusiasm for this approach in light of current concerns regarding the increasing prevalence of antibiotic-resistant organisms. Nonetheless, it may be used in a few highly selected patients whose infections have been defined meticulously (always fulfilling criteria for persistent or severe presentation) and are very frequent (at least 3 infections in 6 months or 4 infections in 12 months). Amoxicillin (20 mg/kg/d given at night) and sulfisoxazole (75 mg/kg/d in 2 divided doses) have been used successfully to prevent episodes of acute otitis media. Usually prophylaxis is maintained until the end of the respiratory season. It is appropriate to initiate an evaluation for factors that commonly predispose to episodes of recurrent acute bacterial sinusitis such as atopy, immunodeficiency, cystic fibrosis, and dysmotile cilia syndrome. Children with craniofacial abnormalities also are at risk to develop acute bacterial sinusitis.

Complementary/Alternative Medicine for Prevention and Treatment of Rhinosinusitis

No recommendations are made based on limited and controversial data.

A substantial number of children, adolescents, and their parents use nonprescription cold medicines or simple home-based remedies such as soups, fruit juices, or teas as alternatives or complements to conventional therapy for the treatment of upper respiratory infections including rhinosinusitis Others use herbal remedies and nutritional supplements or seek care from acupuncturists, chiropractors, homeopaths, naturopaths, aromatherapists, massage and therapeutic touch practitioners, and a variety of other healing modalities.

Few of these therapies for upper respiratory tract infection or rhinosinusitis have been validated in randomized controlled trials. Claims that homeopathic medicines, vitamin C preparations, or zinc lozenges prevent upper respiratory infections or hasten their resolution are controversial. A recently published study provides evidence that zinc nasal gel is effective in shortening the duration of symptoms of the common cold when taken within 24 hours of their onset. Studies performed among adults indicating efficacy of Echinacea preparations in stimulating the immune system, thereby reducing the incidence, duration, or severity of respiratory infections, are debated; however, a recent meta-analysis suggested a predominance of generally positive effects.

Physicians treating children and young adults should be aware that many of their patients are using complementary therapies, often without informing them. Most of these remedies are harmless and, whether through pharmacologic or placebo effect, a perception of efficacy in providing relief from symptoms has stood the test of time. Nevertheless, many herbal medicines sold in the United States are of uncertain efficacy, content, and toxicity and carry a potential for serious adverse effects. Of particular concern is the ability of the botanicals, either by direct interaction or by altering excretion mechanisms, to magnify or oppose the effect of conventional medicines that patients may be using concurrently. Physicians should inquire about the use of complementary medicine for upper respiratory tract infections among their patients, particularly those on long-term medication for chronic conditions. Information on dietary supplements is available on a regularly updated Internet site (Office of Dietary Supplements International Bibliographic Information on Dietary Supplements [IBIDS] Database.

Recommendation 4

Children with complications or suspected complications of acute bacterial sinusitis should be treated promptly and aggressively. This should include referral to an otolaryngologist usually with the consultation of an infectious disease specialist, ophthalmologist, and neurosurgeon (strong recommendation based on strong consensus of the panel).

The complications of acute bacterial sinusitis usually involve either the orbit, the central nervous system, or both. Although rare, complications can result in permanent blindness or death if not treated promptly and appropriately.

Periorbital and intraorbital inflammation and infection are the most common complications of acute sinusitis and most often are caused by acute ethmoiditis. These disorders are commonly classified in relation to the orbital septum. The orbital septum is a sheet of connective tissue continuous with the periosteum of the orbital bones that separates tissues of the eyelid from those of the orbit. Preseptal inflammation involves only the eyelid, whereas postseptal inflammation involves structures of the orbit. Complications can be classified as (1) periorbital (or preseptal) cellulitis or sympathetic edema (periorbital cellulitis is not a true orbital complication. The periorbital swelling is attributable to passive venous congestion; infection is confined to the paranasal sinuses), (2) subperiosteal abscess, (3) orbital abscess, (4) orbital cellulitis, or (5) cavernous sinus thrombosis.

Mild cases of periorbital cellulitis (eyelid <50% closed) may be treated with appropriate oral antibiotic therapy as an outpatient with daily patient encounters. However, if the patient has not improved in 24 to 48 hours or if the infection is progressing rapidly, it is appropriate to admit the patient to the hospital for antimicrobial therapy consisting of intravenous ceftriaxone (100 mg/kg/d in 2 divided doses) or ampicillin-sulbactam (200 mg/kg/d in 4 divided doses). Vancomycin (60 mg/kg/d in 4 divided doses) may be added in children in whom infection is either known or likely to be caused by Streptococcus pneumoniae that are highly resistant to penicillin.

If proptosis, impaired visual acuity, or impaired extraocular mobility are present on examination, a computed tomography scan (preferably coronal thin cut with contrast) of the orbits/sinuses is essential to exclude a suppurative complication. In such cases, the patient should be evaluated by an otolaryngologist and an ophthalmologist. Suppurative complications generally require prompt surgical drainage. An exception to this is the patient with a small subperiosteal abscess and minimal ocular abnormalities for whom intravenous antibiotic treatment for 24 to 48 hours is recommended while performing frequent visual and mental status checks. Patients who have changes in visual acuity or mental status or who fail to improve within 24 to 48 hours require prompt surgical intervention and drainage of the abscess. Antibiotics can be altered, if inappropriate, when results of culture and sensitivity studies become available.

In patients with altered mental status, neurosurgical consultation is indicated. Signs of increased intracranial pressure (headache and vomiting) or nuchal rigidity require immediate computed tomography scanning (with contrast) of the brain, orbits, and sinuses to exclude intracranial complications such as cavernous sinus thrombosis, osteomyelitis of the frontal bone (Pott's puffy tumor), meningitis, subdural empyema, epidural abscess, and brain abscess. Central nervous system complications, such as meningitis and empyemas, should be treated either with intravenous cefotaxime or ceftriaxone and vancomycin pending the results of culture and susceptibility testing.

CLINICAL ALGORITHM(S)

An algorithm is provided for the management of children with uncomplicated acute bacterial sinusitis.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations contained in this practice guideline are based on the best available data. Where data are lacking, a combination of evidence and expert opinion was used. Strong recommendations were based on high-quality scientific evidence or, when such was unavailable, strong expert consensus. Fair and weak recommendations are based on lesser-quality or limited data and expert consensus. Clinical options are identified as interventions for which the subcommittee could not find compelling positive or negative evidence. These clinical options are interventions that a reasonable health care professional may or may not wish to consider.

The 21 qualifying studies examined for this guideline included 5 controlled randomized trials, 8 cases series on antimicrobial therapy, 3 controlled randomized trials on ancillary treatments, and 8 studies with information on diagnostic tests.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate diagnosis of bacterial sinusitis, appropriate use of imaging procedures, and judicious use of antibiotics.

Subgroups Most Likely to Benefit:

Children 6 years of age or younger (because the peak age for acute bacterial sinusitis is in children 6 years of age or younger).

POTENTIAL HARMS

Hypersensitivity and allergic reactions to amoxicillin or other antibiotics.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

This clinical practice guideline is not intended as a sole source of guidance in the diagnosis and management of acute bacterial sinusitis in children. It is designed to assist pediatricians by providing an analytic framework for evaluation and treatment. It is not intended to replace clinical judgment or establish a protocol for all patients with this condition.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Clinical practice guideline: management of sinusitis. Pediatrics 2001 Sep;108(3):798-808. [79 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Sep

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

To develop the clinical practice guideline on the management of acute bacterial sinusitis, the American Academy of Pediatrics subcommittee partnered with the Agency for Healthcare Research and Quality and colleague organizations from family practice and otolaryngology. The Agency for Healthcare Research and Quality (AHRQ) worked with the New England Medical Center Evidence-based Practice Center, as one of several centers that focus on conducting systematic reviews of the literature. A full report was produced by the New England Medical Center on the diagnosis and management of acute sinusitis (see "Companion Documents").

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Subcommittee on Management of Sinusitis

Committee on Quality Improvement

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

AAP Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Technical report: evidence for the diagnosis and treatment of acute uncomplicated sinusitis in children: a systematic overview. Pediatrics 2001 Sep;108(3):E57. Available from the American Academy of Pediatrics (AAP) Policy Web site.
- Diagnosis and treatment of uncomplicated acute sinusitis in children. Rockville, MD: Agency for Healthcare Research and Quality, US Department of Health and Human Services; 2000. (Evidence report/technology assessment: no. 9). AHRQ Contract No. 290-97-0019.

Electronic copies: Available in summary form from the Agency for Healthcare Research and Quality (AHRQ) Web site; this document is also available in full text from the National Library of Medicine's Health Services/Technology Assessment Text (HSTAT) Web site.

Print copies: Available from AAP, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 16, 2001. The information was verified by the guideline developer as of December 5, 2001.

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